

REMARKS

Claims 1 through 12 have been rejected. No claims have been allowed. Claims 13-32 have been added.

In response to the Examiner's objection to the lack of an Abstract of the disclosure, the Applicants enclose herewith an Abstract on a separate sheet of paper.

1. **Claim Rejections -35 U.S.C. § 112**

Claims 1-12 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Claims 1-12 have been canceled. Applicants have submitted new Claims 13-32 and submit that the claims meet the requirements of 35 U.S.C. § 112.

2. **Deposit** ( ) !

Claims 8-11 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants submit that the requirements of 35 U.S.C. § 112 have been satisfied because all of the microorganisms utilized in the present invention are on deposit at an International Depository Authority (IDA) as set forth in MPEP § 2405.

The strains <sup>not claimed</sup> TL 221, <sup>not claimed</sup> TL 223 and <sup>not claimed</sup> TL 207, belonging, respectively, to the species *P. thoenii*, *P. acidipropionici* and *P. jensenii* belong to the INRA-LRTL. Strain P 23 is registered at the Collection Nationale des Cultures de Micro-organismes (National Collection of Microorganisms Cultures (CNCM)) of the Institut Pasteur under the number 1-1804. The strains CNRZ86 and CNRZ287, belonging to the species *P. acidipropionici*, are part of the INRA-CNRZ public collection. The strains CNRZ 81, CNRZ 89 and CNRZ 277, belong to the species *P. freudenreichii*, and are also part of the INRA-CNRZ public collection. The strain NCDO 1072, belonging to the species *P. acidipropionici* belongs to the British collection "National Collection of Dairy Organisms."

what is ?  
INRA-LRTL

see str. 1  
page 16

not claim

what is in NCIMB  
"NCDO"?

only CNCM on ID #1804

**3. Claim Rejections- 35 U.S.C. § 102(b)**

The Examiner has rejected Claims 1-7 and 12 as being anticipated by U.S. Patent No. 4,379,170 to Hettinga et al. Claims 1-12 have been canceled.

U.S. Patent No. 4,379,170 to Hettinga et al. discloses, in pertinent part, a process for the manufacture of a Swiss or Emmental flavored cheese product in which a mixture containing skim milk is fermented with 80 ppm of Rhozyme P-11 and 6.6% inoculum of a 50/50 mixture of Propionibacteria P16 and P20 (G-broth, 6.2 X 10<sup>9</sup> cells per gram of P16, 1.2 X 10<sup>9</sup> cells per gram of P20) for 5 hours.

Claim 13 (which replaced Claim 1) discloses a dietary supplement for human and animal consumption which comprises more than 10<sup>9</sup> cells/gram of propionibacteria, and is capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

Applicants admit that propionibacteria has been utilized for centuries in the preparation and maturation process of some cooked cheeses such as Gruyere or Emmental. However, Applicants respectfully submit that Hettinga et al. does not contemplate nor disclose the ability of propionibacteria to release any nitric oxide, let alone disclose its ability to release a physiologically significant amount of nitric oxide into the human or animal digestive tract, as disclosed in Claim 13.

In response to the Examiner's 35 U.S.C. § 102 (b) rejection, Applicants respectfully remind the Examiner that "[a] rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 1478 (Fed. Cir. 1994). In light of the foregoing, Applicants respectfully submit that because Hettinga et al. does not disclose the ability of propionibacteria to release any nitric oxide, let alone disclose its ability to release a physiologically significant amount of nitric oxide into the human or animal digestive tract, Hettinga et. al. does not teach every element of the claimed invention. Therefore, Claim 13 is not anticipated or rendered obvious by Hettinga et al.

The Examiner has rejected Claims 1-8, 10 and 11 as being anticipated by U.S. Patent No. 5,573,947 to Madec et. al.

U.S. Patent No. 5,573,947 to Madec et. al. discloses the use of a selective culture medium which permits the counting of propionic bacteria under anaerobic conditions for improving the preparation of cooked cheeses, specifically Gruyere or Emmental cheeses.

Claim 13 (which replaced Claim 1) discloses a dietary supplement for human and animal consumption which comprises more than  $10^9$  cells/gram of propionibacteria, and is capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

Applicants respectfully submit that Madec et al. does not contemplate nor disclose the ability of propionibacteria to release any nitric oxide, let alone disclose its ability to release a physiologically significant amount of nitric oxide into the human and animal digestive tract, as called for in Claim 13.

A rejection for anticipation under §102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. Madec et al. does not disclose the ability of propionibacteria to release any nitric oxide, let alone disclose its ability to release a physiologically significant amount of nitric oxide into the human and animal digestive tract. Therefore, Claim 13 is not anticipated nor rendered obvious by Madec et al.

**4. Claim Rejections- 35 U.S.C. § 103(a)**

The Examiner has rejected Claims 1-12 as being unpatentable over U.S. Patent No. 4,379, 170 to Hettinga et al. taken with U.S. Patent No. 5,573,947 to Madec et al. and Balows et al.

Balows et al. (page 556, 2nd paragraph) discusses generally that certain propionic bacterium have been found to participate in nitrate reducing activity and may induce denitrification processes. Additionally, Balows et al. discloses that certain propionic bacteria are capable of reducing nitrates into gaseous products.

As discussed hereinabove, Hettinga et. al. discloses, in pertinent part, a process for the manufacture of a Swiss or Emmental flavored cheese product in which a mixture containing skim milk is fermented with 80 ppm of Rhozyme P-11 and 6.6% inoculum of a 50/50 mixture of Propionibacteria P16 and P20 (G-broth,  $6.2 \times 10^9$  cells per gram of P16,  $1.2 \times 10^9$  cells per gram of P20) for 5 hours.

Also as discussed hereinabove, Madec et. al. discloses the use of a selective culture medium which permits the counting of propionic bacteria under anaerobic conditions for improving the preparation of cooked cheeses, specifically Gruyere or Emmental cheeses.

Claim 13 calls for a composition for use as a dietary supplement comprising more than  $10^9$  cells/gram of propionibacteria which is capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

Balows et. al. fails to disclose the ability of propionibacteria to accumulate and release nitric oxide in the form of a stable compound. Rather, nitric oxide is generally an unstable and fleeting intermediary. Balows et. al. also fails to disclose the use of more than  $10^9$  cells/gram of propionibacteria for the purpose of releasing physiologically significant amounts of nitric oxide into the human and animal digestive tract, as called for in Claim 13.

6-10's  
1.2-10's  
= 7-10's  
7 hrs more  
from 10's

Hettinga et al. and Madec et al. also fail to disclose the use of more than  $10^9$  cells/gram of propionibacteria for the purpose of releasing physiologically significant amounts of nitric oxide into the human and animal digestive tract, as called for in Claim 13. Furthermore, Applicants respectfully submit that neither Balows et. al., Hettinga et. al., nor Madec et. al. contain any suggestions or motivation to combine their teachings in order to render obvious Applicants' invention as set forth in Claim 13.

35 U.S.C. § 103 (a) provides that an invention is not patentable if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Furthermore, a "[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546, 48 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 1998). Rather, prior art references are properly combined only where there is a suggestion, teaching, or motivation to combine them, and that suggestion, teaching, or motivation comes from the prior art references themselves. C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998).

Because the suggestion, teaching, or motivation to combine references must come from within the references themselves, and the cited references do not contain such a suggestion, teaching, or motivation, Claim 13 is not rendered obvious over Hettinga et. al.

taken with Madec et al. and Balows et. al. Even if the teachings of Balows et. al., Hettinga et. al., and Madec et. al. are combined, the resulting teaching does not disclose the ability of propionibacteria to release a physiologically significant amount of nitric oxide into the human and animal digestive tract. Thus, Applicants submit that Claim 13 is patentable over the cited references, individually or in combination.

Claim 18 calls for a dietary supplement comprising a sufficient quantity of propionibacteria and one or more selected from the group consisting of bifidobacteria and lactic acid bacteria. The composition is capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract. Balows et al., Hettinga et. al., and Madec et. al. each fail to disclose a composition capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract which comprises a sufficient quantity of propionibacteria and one or more selected from the group consisting of bifidobacteria and lactic acid bacteria. Applicants submit that Hettinga et. al., Madec et. al., and Balows et. al., taken either individually or in combination, do not teach Applicants' claimed invention. Thus, Applicants submit that Claim 18 is patentable over the cited references, individually or in combination.

Claim 20 calls for a method of making a composition for use as a dietary supplement which comprises the steps of providing a supply of propionibacteria and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and digestive tract. Hettinga et al., Madec et. al., and Balows et al. each fail to disclose a method of making a composition for use as a dietary supplement comprising the steps of providing and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract. Applicants submit that Hettinga et. al., Madec et. al., and Balows et. al., taken either individually or in combination, do not teach Applicants' claimed invention. Thus, Applicants submit that Claim 20 is patentable over the cited references, individually or in combination.

Claim 25 calls for a method of making a food composition for use as a dietary supplement which comprises the steps of providing a supply of propionibacteria; selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract; and adding the propionibacteria to a food product selected from the list of cheeses, sources of dietary fibre, fermented milk, dessert

cream, cake, and tonic drink. Hettinga et. al., Madec et. al., and Balows et al. each fail to disclose a method of making a food composition for use as a dietary supplement comprising the steps of providing and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract; and adding the propionibacteria to a food product selected from the list of cheeses, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink. Applicants submit that Hettinga et. al., Madec et. al., and Balows et. al., taken either individually or in combination, do not teach Applicants' claimed invention. Thus, Applicants submit that Claim 25 is patentable over the cited references, individually or in combination.

Claim 29 calls for a method of making a composition for use as a dietary supplement which comprises the steps of providing a supply of propionibacteria and at least one of the group consisting of bifidobacteria and lactic acid bacteria, and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract. Hettinga et. al., Madec et. al., and Balows et al. each fail to disclose a method of making a composition for use as a dietary supplement comprising the steps of providing a supply of propionibacteria and at least one of the group consisting of bifidobacteria and lactic acid bacteria; and selecting an amount of propionibacteria sufficient to release physiologically significant amounts of nitric oxide into the human and animal digestive tract. Applicants submit that Hettinga et. al., Madec et. al., and Balows et. al., taken either individually or in combination, do not teach Applicants' claimed invention. Thus, Applicants submit that Claim 29 is patentable over the cited references, individually or in combination.

Claims 14-18 depend from Claim 13. Applicants therefore submit that Claims 14-18 are also not obvious over any combination of Hettinga et. al., Madec et. al., and Balows.

Claims 21-24 depend from Claim 20, Applicants therefore submit that Claims 21-24 are also not obvious over any combination of Hettinga et. al., Madec et. al., and Balows.

Claims 26-28 depend from Claim 25, Applicants therefore submit that Claims 26-28 are also not obvious over any combination of Hettinga et. al., Madec et. al., and Balows et. al.

Claims 30-32 depend from Claim 29, Applicants therefore submit that Claims 30-32 are also not obvious over any combination of Heating et. al., Made et. al., and Blows et. al.

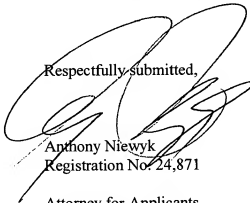
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In view of the foregoing, Applicants submit that all claims at issue are in condition for allowance and respectfully requests allowance thereof.

Should any questions concerning any of the foregoing arise, the Examiner is invited to telephone the undersigned at (219) 460-1695.

In the event the Applicants have overlooked the need for an extension of time, an additional extension of time, or payment of fee or additional payment of fee, Applicants hereby petition therefore and authorizes any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

Respectfully submitted,



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ANTHONY NIEWYK, REG. NO. 24,871

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SIGNATURE

November 17, 2000